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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/054,447	01/22/2002	James R. Keogh	P0009170.00	5485

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MEDTRONIC, INC.
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EXAMINER	
AL-AWADI, DANAH J	

ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
07/07/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/054,447	KEOGH ET AL.	
	Examiner	Art Unit	
	DANAH AL-AWADI	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11/21/2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8,10,233,273-275,279-281 and 293-296* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,10,233,273-275,279-281 and 293-296* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of Applicant's amendments and remarks filed 11/21/2008. The Examiner acknowledges the following:

Claim 9, 11-232, 234-272, 276-278, 282-292, 297 and 298 have been previously cancelled.

Claims 4, 275, and 295 have been amended. The amendment deleted the phrase "a MP35N stainless steel" from the pending claims.

Thus, claims 1-8, 10, 233, 273-275, 279-281 and 293-296 now represent all claims currently pending.

INFORMATION DISCLOSURE STATEMENT

No new Information Disclosure Statements (IDS) have been submitted for consideration.

WITHDRAWN OBJECTIONS/REJECTIONS

Specification

Applicants' amendments to the specification, as well as in light of the publicly available information provided, render moot the objection to the specification. Thus, said objection has been **withdrawn.**

Rejection under 35 USC 112 First Paragraph

Applicants' amendments to the instant claims, , namely claims 4 and 275, and 296, as well as in light of the publicly available information provided, render moot the rejection to

claims 4,275, and 295, under 35 USC 112 First Paragraph as failing to comply with the written description requirement. Thus, said rejection has been **withdrawn.**

MAINTAINED REJECTIONS

No objections/rejections have been maintained from the previous Office Action dated 09/08/2008. All previous objections/rejections have been withdrawn.

NEW REJECTIONS

After further consideration, the following new rejections have been added:

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).Claims 1-8, 233, 273- 275,279, 280,293-295, and 296 are rejected on the ground of

nonstatutory obviousness-type double patenting as being unpatentable over claims 1,4-6 , and 9-14 , of U.S. Patent No. 6,617,142 in view of Klabunde et al. 1998 and Rombi US Patent 6,814,986.

Regarding pending claim 1, Keogh et al. US Patent 6617142 teaches a method for forming a coating on a surface of a medical device. The medical device surface has a chemical moiety that reacts with a guanidine moiety (abstract).

The abstract further states that biomolecules may be crosslinked by combining the guanidine-functional biomolecule with a biomolecule having a chemical moiety that forms a chemical bond with an guanidine moiety.

The invention of the '142 patent provides methods for making a medical device having at least one biomolecule immobilized on a biomaterial surface (paragraph line 38 column 3). The method includes combining a guanidino-functional material with a medical device biomaterial surface comprising a chemical moiety which is capable of forming a chemical bond with the guanidine-functional material (the paragraph of line 1, column 4). The '142 patent states that a hydrophilic environment on the biomaterial surface is preferred (the paragraph of line 25, column 6). The '142 patent is directed towards hydrophilic substrate surfaces (the paragraph of line 44 column 6), and that biomolecules used may be polysaccharides which may be found in nature, or chemically synthesized (the paragraph of line 48 column 5).

Regarding pending claim 2 the '142 patent teaches that the medical device can be blood oxygenators, blood pumps, blood sensors, tubing used to carry blood and the like which contact blood which is then returned to the patient, an extracorporeal device, endoprostheses such as

vascular grafts, stents, pacemaker leads, heart valves, devices for temporary intravascular use such as catheters and guide wires (the paragraph of line 66 column 13).

With regards to pending claim 3, the '142 patent teaches that one method of the invention may be used to modify substrates of any shape or form including tubular, sheet, rod and articles of proper shape for use in a number of medical devices (the paragraph of line 34 column 14). Furthermore, claim 13 of the '142 patent states that a portion of the surface forms at least one of a tube, rod, a membrane, balloon, a bag, and a sheet.

With regards to pending claim 4, the '142 patent teaches the biocompatible material can be titanium, titanium alloys, TiNi alloys, shape memory alloys, aluminum oxide, platinum, platinum alloys, a stainless steel, a cobalt-chromium alloy, pyrolytic carbon, silver carbon, glassy carbon, a polyamide, a polycarbonate, a polyether, a polyester, a polyolefin, a polyethylene, a polypropylene, a polystyrene, a polyurethane, a polyvinylchloride, a polyvinylpyrrolidone, a silicone elastomer, a fluoropolymer, a polyacrylate, a polyisoprene, a polytetrafluoroethylene, a rubber, a ceramic , a hydroxapatite, a bone, a skin, a tooth, a collagen, a laminin, a elastin, a fibrin, a cellulose, a compressed carbon and a glass (the paragraph of line 66 column 13).

With regards to pending claim 5-7, the limitations for the hydrophilic polymer have been discussed supra with pending claim 1.

With regards to pending claim 8, it would have been obvious to one of ordinary skill in the art at the time the invention was made to optimize the molecular weight based on altering the reaction times to formulate a hydrophilic polymer with a molecular weight between about 100,000 and 2,000,000.

The '142 patent discloses that the biomolecules can be can be a 1, 2-dihydroxy moiety (the paragraph of line 32, column 13). The '142 patent does not explicitly disclose that the biomolecule can be catechol, however it would have been prima facie obvious at the time the invention was made to one of ordinary skill in the art to select a catechol moiety for the 1,2 dihydroxy moiety. One would have been motivated to do so because Klabunde et al. " Crystal Structure of a Plant Catechol Oxidase Containing a Dicopper Center" teaches that tyrosinase enzyme is naturally found in the human body and degrades catechol. It would have been obvious to select catechol because catechol is known to be biocompatible and biodegradable in the human body. Furthermore the prior art teaches catechol moieties have positive physiological effects. For example, Rombi US Patent 6,814,986 teaches that catechols are a useful medicinal product which has anti-lipase/thermogenic properties.

Claims 10 and 281 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4-6 , and 9-14 , of U.S. Patent No. 6,617,142 in view of klabunde et al. 1998 and Rombi US Patent 6,814,986 and Hostettler et al. US Patent 6040058.

Claims 10 and 281 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keogh et al. US Patent 6617142, klabunde et al. 1998, and Rombi US Patent 6,814,986. as applied to claims 1-8 above, and further in view of Hostettler et al. US Patent 6040058.

For the limitations of pending claims 10, 233, 273,274,275,279, 280,293,294,295and 296 the combination of the '142 patent and Klabunde et al. has been discussed supra. The combination of patent and Klabunde et al. do not disclose a primer layer, however Hostettler et

al. US Patent 6040058 (hereafter the '058 patent) discloses a primer layer for a substrate surface (the paragraph of line 7 column4).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to formulate a medical device with a primer disposed on the surface of a medical device. One would have been motivated to do so because the '058 patent teaches the advantage of primer layers is that they are used to affect better adhesion of the coating to the substrate.

Claim Rejections - 35 USC § 112 First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1,10, 233,279 and 281, are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. It is unclear what is meant by "catechol moiety". There is no support in the specification for how the catechol moiety is formed. It is unclear where it would attach to a molecule, and what forms the catechol moiety. Furthermore, the specification teaches that it is well know in the art how to coat metal surfaces with catechols but there is no citation of prior art.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-8, 233, 273,274,275,279, 280,293,294,295, and 296 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keogh et al. US Patent 6,617,142, Klabunde et al. 1998, and Rombi US Patent 6,814,986.

Regarding pending claim 1, Keogh et al. US Patent 6617142 teaches a method for forming a coating on a surface of a medical device. The medical device surface has a chemical moiety that reacts with a guanidine moiety (abstract).

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Regarding pending claim 2 the '142 patent teaches that the medical device can be blood oxygenators, blood pumps, blood sensors, tubing used to carry blood and the like which contact blood which is then returned to the patient, an extracorporeal device, endoprostheses such as vascular grafts, stents, pacemaker leads, heart valves, devices for temporary intravascular use such as catheters and guide wires (the paragraph of line 66 column 13).

With regards to pending claim 3, the '142 patent teaches that one method of the invention may be used to modify substrates of any shape or form including tubular, sheet, rod and articles of proper shape for use in a number of medical devices (the paragraph of line 34 column 14). Furthermore, claim 13 of the '142 patent states that a portion of the surface forms at least one of a tube, rod, a membrane, balloon, a bag, and a sheet.

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carbon, a polyamide, a polycarbonate, a polyether, a polyester, a polyolefin, a polyethylene, a polypropylene, a polystyrene, a polyurethane, a polyvinylchloride, a polyvinylpyrrolidone, a silicone elastomer, a fluoropolymer, a polyacrylate, a polyisoprene, a polytetrafluoroethylene, a rubber, a ceramic , a hydroxapatite, a bone, a skin, a tooth, a collagen, a laminin, a elastin, a fibrin, a cellulose, a compressed carbon and a glass (the paragraph of line 66 column 13).

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It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to formulate a medical device with a primer disposed on the surface of a medical device. One would have been motivated to do so because the '058 patent teaches the advantage of primer layers is that they are used to affect better adhesion of the coating to the substrate.

All claims have been rejected; no claims are allowed.

CORRESPONDENCE

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Danah Al-awadi whose telephone number is (571) 270-7668. The examiner can normally be reached on 9:00 am - 6:00 pm; M-F (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Danah Al-Awadi/
Examiner, Art Unit 1615

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615